

VALIDATION RESULTS FOR METHOD NO. Covance Harrogate 2001-042-D2					
		MEAN	RELATIVE STD. DEV.(%)	RANGE	SEE (conc)
ANALYTE	3-Hydroxycotinine				
MATRIX	Human urine				
DATE	10-Aug-01				
LLOQ	1.0 ng/mL Accuracy 112.0% RSD 10.4%				
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) (SEE = S.D./SQRT (# of determinations))					
	2 ng/mL	Low QC			0.102
	400 ng/mL	Med QC			8.821
	750 ng/mL	High QC			7.405
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quadratic, etc.)	Linear				
Slope (mean)	0.0539				
Intercept (mean)	0.0026				
Other (mean regression value)	0.9982(1/x weighted)				
RECOVERY (as a %)					
High QC in (matrix)=	750 ng/mL	20.1%			
Med QC in (matrix)=	400 ng/mL	21.1%			
Low QC in (matrix)=	2 ng/mL	29.0%			
Results with different sample amounts (results of QC evaluations) intra-assay					
LLOQ QC=	1 ng/mL	1.12	10.4%	0.99-1.28	0.047
Low QC=	2 ng/mL	2.2	13.7%	1.71-2.53	0.123
Med QC=	400 ng/mL	383.39	8.5%	351.40-434.41	13.227
High QC=	750 ng/mL	671.54	1.9%	657.81-690.68	5.334
Results with different sample amounts (results of QC evaluations) inter-assay					
LLOQ QC=	n/a	n/a	n/a	n/a	n/a
Low QC=	2 ng/mL	2.13	11.7%	1.53-2.53	0.102
Med QC=	400 ng/mL	370.27	5.8%	345.33-434.41	8.821
High QC=	750 ng/mL	673.74	2.7%	637.29-710.23	7.405
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)		12.5% maximum			
b) Freeze/thaw (+/- % /3 cycles)		4.6% maximum			
c) Injector (+/- %/24 hrs)	Refrigerated 68 hrs	2.3% maximum			